PRESS RELEASE

REGULATED INFORMATION
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BIOCARTIS MEETS 2021 KEY OBJECTIVES

Mechelen, Belgium, 10 January 2022 - Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), announced the Company has achieved its 2021 key business objectives which were focused on three performance indicators: expanded installed base of its rapid and easy-to-use Idylla™ molecular diagnostics platform, increased Idylla™ commercial cartridge volume and its year-end cash position.

Based on non-audited numbers, Biocartis today reports:

- *Installed base* – Biocartis placed 331 net new Idylla™ instruments in 2021, in line with the latest guidance of 300-350 new instrument placements. Biocartis' installed base as per 31 December 2021 increased to 1,912 Idylla™ instruments.
- *Cartridge volume* – In 2021, Biocartis sold 323k commercial cartridges, 40% more than in 2020 and in line with the latest guidance. Continued strong growth in oncology, was complemented by a consistent contribution of the Idylla™ SARS-CoV-2 tests[1] and initial sales of SeptiCyte® RAPID on Idylla™.
- *Cash position* – As per 31 December 2021, Biocartis' cash[2] position amounted to EUR 53.5m (non-audited number) versus the latest guidance of EUR 50m. The cash position included EUR 6.0m drawn on short-term credit facilities. The cash burn for the year was in line with expectations, except for the insurance claim for fire damages that is not fully collected yet.

Herman Verrelst, Chief Executive Officer of Biocartis, commented: *"We delivered on our growth objectives for 2021, and would have grown even faster if production on our high-throughput cartridge manufacturing line would not have been halted for two months as a consequence of the fire. The team did a tremendous job in overcoming the production stop and the temporary shortage of raw materials, and the backlog of customer orders is almost entirely caught-up. Working closely with our customers, we continued our mission to enable access to personalized medicine for patients across the globe through more, better and faster molecular diagnostics. We maintained our strategic focus on developing, together with partners, high-value Idylla™ test content in oncology in combination with a growing infectious disease test menu for acute settings where patients today lack essential information for rapid treatment decisions. We came out 2021 stronger and more resilient as a company, and as we look ahead, we aim to multiply growth and unlock additional value creating opportunities as we drive further adoption of our transformational platform technology in the months and years ahead."*

In 2021, Biocartis made significant progress in expanding its test menu, a key driver of profitable growth. Achievements included the following:

- *Oncology*:
  - In March 2021, Biocartis launched the Idylla™ GeneFusion Assay (RUO[3]) as a rapid lab workflow solution for gene fusion testing of ALK, ROS1, RET, NTRK 1/2/3, as well as MET exon 14 skipping which is increasingly used in research related to multiple cancer types including lung cancer, thyroid cancer and others;
  - In April 2021, Biocartis announced its first US FDA submission of an oncology assay with the 510(k) submission[4] of its Idylla™ MSI Test for use as an *in vitro* diagnostic device intended for the identification of microsatellite instability (MSI) status in colorectal (colon) cancer (CRC) to aid in the differentiation between sporadic CRC and potential Lynch syndrome;
  - Also in April 2021, Biocartis announced the signing of a partnership agreement with SkylineDx which targets the development of their novel proprietary test, the Merlin Assay, on the Idylla™ platform, which is aimed at predicting a patient's risk of nodal metastasis in melanoma;
  - In May 2021, Biocartis announced its expanded partnership with AstraZeneca to improve access to rapid and easy-to-use Idylla™ EGFR testing products at selected hospital sites in European and global distributor markets[5];
  - Also in May 2021, Biocartis announced the EUR 1.4 million grant it received from VLAIO, the Flanders organization for Innovation & Entrepreneurship, for the ongoing development of a highly innovative technology to be deployed on the Idylla™ platform aimed at enabling the off-line customization of the Idylla™ cartridge.

1 In the US, distribution of the Idylla™ SARS-CoV-2 Test was initiated in Q3 2020 per US FDA Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised), May 2020, Section IV.C. Commercial Manufacturer Development and Distribution of Diagnostic Tests Prior to EUA Submission
2 Consisting of cash and cash equivalents
3 Research Use Only, not for use in diagnostic procedures
4 A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). A 510(k) or Premarket Notification (PMN) with the US FDA is required when introducing a device into commercial distribution for the first time. Source: https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances, last consulted on 4 January 2022
5 Defined as the world excluding European direct markets, US, China and Japan

- *Infectious diseases*:
  - In September 2021, Biocartis announced the launch of its Idylla™ SARS-CoV2/Flu/RSV Panel (CE-IVD) which detects, in one single cartridge, SARS-CoV-2, Flu A/B and RSV[6] nucleic acids, with results in approximately 90 minutes;
  - In November 2021, Biocartis announced the US FDA granted 510(k) clearance for SeptiCyte® RAPID[7] (CE-IVD, US FDA 510(k)) which runs on the Idylla™ platform[8] and was developed under the partnership with Immunexpress[9]. The SeptiCyte® RAPID is a fully automated, rapid host-response test[10] that distinguishes sepsis from infection negative systemic inflammation in patients suspected of sepsis, providing actionable results in approximately 1 hour, enabling physicians to optimize patient management decisions;
  - In December 2021, Biocartis announced the successful performance of an in-silico analysis concluding that the Idylla™ SARS-CoV-2 Test (CE-IVD) and Idylla™ SARS-CoV-2/Flu/RSV Panel (CE-IVD) are both able to detect the B.1.1.529/Omicron sequences, the latest variant of concern causing COVID-19 disease.
- *Idylla™ publications* – In 2021, Idylla™'s excellence along with the performance of Idylla™'s EGFR[11] testing solutions was emphasized through several studies and abstracts:
  - In February 2021, Biocartis announced the publication of two studies[12] by Memorial Sloan Kettering Cancer Center ('MSKCC', New York, US) on the use of Biocartis' Idylla™ EGFR Mutation Assay (RUO) as a rapid first-line testing method before using next-generation sequencing (NGS). Both studies concluded that Idylla™ EGFR testing enables rapid assessment of the most common EGFR mutations with low sample input, even on different sample types, without compromising subsequent more comprehensive NGS testing[13];
  - In November 2021, Biocartis announced the publication of a study[14] which concluded that the Idylla™ platform contributes to improving patient management decisions for patients with non-small cell lung cancer (NSCLC) through the faster screening of EGFR mutations.

Biocartis will publish its 2021 full year results and 2022 guidance on 24 February 2022.

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About Biocartis
Biocartis (Euronext Brussels: BCART) is an innovative molecular diagnostics (MDx) company providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry. Biocartis' proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample in virtually any setting. Biocartis is developing and marketing a continuously expanding test menu addressing key unmet clinical needs, with a focus in oncology, which represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer, as well as for COVID-19, flu, RSV and sepsis. More information: www.biocartis.com. Follow us on Twitter: @Biocartis_.

6 Respiratory Syncytial Virus
7 SeptiCyte® RAPID is developed by Immunexpress Inc in collaboration with Biocartis. Biocartis has the exclusive distribution rights for the EU. The test is not available in all countries. Availability to be checked with a local Biocartis representative
8 The Idylla™ Instrument and Idylla™ Console have been exempted by the US FDA since 12 July 2017 and as such are not subject to 510(k) notification requirements prior to being placed on the US market for in vitro diagnostic use with US FDA approved or cleared assays
9 Immunexpress Pty Ltd ('Immunexpress') is a Seattle-based molecular diagnostic company focused on improving outcomes for suspected sepsis patients
10 Host-response based tests focus on measuring biomarkers that are indicative of the response of a patient's immune system to an infection rather than measuring pathogens that are the cause of the infection
11 EGFR or 'Epidermal growth factor receptor' mutations are the second most common oncogenic driver in non-small cell lung cancer (NSCLC)
12 Arcila ME, Yang S-R, Momeni A, Mata DA, Salazar P, Chan R, Elezovic D, Benayed R, Zehir A, Buonocore DJ, Rekhtman N, Lin O, Ladanyi M, Nafa K, Ultra-Rapid EGFR Mutation Screening Followed by Comprehensive Next-Generation Sequencing: A Feasible, Informative Approach for Lung Carcinoma Cytology Specimens with a High Success Rate., JTO Clinical and Research Reports (2020), doi: https://doi.org/10.1016/j.jtocrr.2020.100077., available online 18 July 2020; Arcila ME et al., Rapid EGFR Mutation Detection Using the Single-Institution Experience of 1200 Cases Analyzed by an In-House Developed Pipeline and Comparison with Concurrent Next-Generation Sequencing Results Idylla™ Platform, J Mol Diagn 2020, Published on 23 December 2020, 1-12; https://doi.org/10.1016/j.jmoldx.2020.11.009
13 Which can be useful in cases where EGFR mutation results were negative and further testing is needed
14 Petiteau, C.; Robinet-Zimmermann, G.; Riot, A.; Dorbeau,M.; Richard, N.; Blanc-Fournier, C.; Bibeau, F.; Deshayes, S.; Bergot, E.; Gervais, R.; et al. Contribution of the Idylla™ System to Improving the Therapeutic Care of Patients with NSCLC through Early Screening of EGFR Mutations. Curr. Oncol. 2021, 28, 4432–4445. https://doi.org/10.3390/curroncol28060376, published 3 November 2021

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